



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/536,533

11/29/2005

Ganga Prasad Rai

4544-051675

7482

28289 7590 07/27/2010
THE WEBB LAW FIRM, P.C.
700 KOPPERS BUILDING
436 SEVENTH AVENUE
PITTSBURGH, PA 15219

EXAMINER

HINES, JANA A

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

07/27/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/536,533	Applicant(s) RAI ET AL.	
	Examiner JaNa Hines	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-28 is/are pending in the application.
- 4a) Of the above claim(s) 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/31/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 28, 2010 has been entered.

Amendment Entry

2. The amendment of May 28, 2010 has been entered. Claims 23 and 24 have been amended. Claim 28 is withdrawn from consideration. Claims 1-22 are cancelled. Claims 23-27 are under consideration in this office action.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on March 31, 2010 was filed. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Withdrawal of Rejections

4. The following rejection has been withdrawn in view of applicants' amendments and arguments:

a) the rejection of claims 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Lim et al., (J. Clinical Microbio. 1987. Vol. 25(7): 1165-1168).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. The new matter rejection of claim 23 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

Applicants assert that the amendments to the claims overcomes the rejection. However claim 23(c) recites coating a latex particle with the said polyclonal-monospecific antibody specific to *Salmonella typhi*. Therefore it is the Office's position that neither the specification nor originally presented claims provides support for an a process for preparing an agglutination reagent for detecting typhoid comprising coating a latex particle with the polyclonal-monospecific antibody. Therefore applicants' amendment did not overcome the rejection and the rejection is maintained.

New Grounds of Rejection Necessitated By Amendments

Claim Objections

6. Claim 23 is objected to because of the following informalities: Claim 23 (i) drawn to the latex particle coating recites "Flagelling gene of *Salmonella typhicoated* latex particle..." Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 23 recites the limitation "said polyclonal-monospecific antibody specific to *Salmonella typhi*" in the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nilsson et al., (Electrophoresis. 2001. Vol. 22:2384-2390) in view of Sukosol et al..

Claim 24 is drawn to an agglutination reagent for rapid and early detection of typhoid, comprising of a carboxylated latex particles coated with antibody specific to a Flagellin gene of *Salmonella typhi*, suspended in storage buffer. Claim 25 is drawn to the size of the said latex particles is 0.88 to 0.90 μm .

Nilsson et al., teach antibodies-coated particles used in agglutination assays give more rise to limits of detection in the lower attomole regions of fully optimized systems

Art Unit: 1645

(page 2384, col.2). Nilsson et al., teach affinity purified antibodies, carboxylated latex particles, Bovine serum albumin (BSA), TWEEN 20 surfactant, Tris, sodium hydroxide, and other reagents (page 2385, col. 1). The carboxylated latex particles were 0.9um sized (page 2385, col1). Nilsson et al., teach covalent coupling of antibodies to latex particles (page 2385, col.1). Nilsson et al., teach the antibody solution with 1% of carboxylated latex particles suspended in Tris-BSA buffer (page 2385, col. 2). However Nilsson et al., do not teach the antibody specific to a flagellin gene of *Salmonella typhi*.

Sukosol et al., teach the monoclonal antibodies specific to the *S. typhi* 52kDa antigen (page 21, col.1). Sukosol et al., teach specific 52kDa antigen detected by the monoclonal antibodies was *S. typhi* flagellin (page 22, col. 1). The gene was the flagellin gene and the flagellin DNA was amplified using PCR technology (page 22, col.1-3). Sukosol et al., refers to the teaching of Ekpo et al., (J. Clin. Microbiol. 1990. Vol. 28:1818-1821) entitled Monoclonal Antibodies to 52kDa Protein of *S. typhi* as disclosing monoclonal antibodies from hybrid clones specific for *Salmonella typhi* antigen produced by immunizing mice with affinity-purified *S. typhi* protein.

Therefore it would have been prima facie obvious at the time of applicants' invention to apply the antibody specific to a flagellin gene of *Salmonella typhi* as taught by Sukosol et al., the agglutination reagent comprising specific antibody and latex particles as taught by Nilsson et al., in order to advantageously achieve a n agglutination reagent for highly selective and sensitive protein detection and aide in medical diagnosis. One of ordinary skill in the art would have a reasonable expectation of success by exchanging the antibody specific to a flagellin gene of *Salmonella typhi*

Art Unit: 1645

antibody with another antibody because are they are known to be capable of being coated onto latex particles in order to provide specific binding for use in agglutination assays. Furthermore, no more than routine skill would have been required to exchange the antibody of Nilsson et al., for the well known and functionally equivalent antibody Sukosol et al., since the art discloses the benefits of antibodies that specifically bind to flagellin.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 23-24 and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nilsson et al., (Electrophoresis. 2001. Vol. 22:2384-2390) and Sukosol et al., (Asian Pacific J. of Allergy and Immuno. 1994. Vol. 12. pages 21-25) in view of Salzman et al (WO 01/40280 published June 1, 2001) and Fruitstone et al., (US Patent 4,379,847 published April 12, 1983).

Claim 23 is drawn to a process for the preparation of an agglutination reagent for rapid and early detection of typhoid comprising: (a) preparing antibody specific to a flagellin gene of *Salmonella typhi*; (b) preparing latex particles suspension; (c) coating of the said latex particles with the said antibody specific to *S. typhi*; wherein the said antibody specific to the flagellin gene of *S. typhi* is prepared according to a method

Art Unit: 1645

comprising: (i) raising the hyper immune sera against a purified protein encoded by a flagellin gene specific to *S. typhi*, and (ii) separating the antibody specific to the Flagellin gene of *S. typhi* from the hyper immune sera; wherein said latex particle suspension is prepared according to a method comprising: (i) mixing 1% carboxylated latex particles and a 40 mM 2-N morpholinoethane sulphonic acid (MES) buffer of pH 5.5 to 6.0 in a ratio of 1:1, washing with a 20 mM MES buffer of pH 5.5 thereby forming a washed latex particle, and (ii) adding a 1-ethyl-3 (3-dimethyl-amino propyl) carbodiimide hydrochloride (EDC) in a 20 mM MES buffer of pH 5.5 to said washed latex particle in a ratio of 1:1, washing with a 20 mM MES buffer (pH 5.5); and wherein said latex particle is coated according to a method comprising: (i) reacting said antibody specific to the Flagellin gene of *S. typhi* with said washed latex particle thereby forming an antibody specific to the Flagellin gene of *S. typhi* coated latex particle, (ii) stopping the reacting step (i) by adding 1M glycine (pH 11.0), and (iii) washing said antibody specific to the Flagellin gene of *S. typhi* coated latex particle with a washing buffer comprised of 50 mM glycine, pH 8.5; 0.03% surfactant and 0.05% sodium azide.

Claim 24 is drawn to an agglutination reagent for rapid and early detection of typhoid, comprising of 1% carboxylated latex particles coated with antibody specific to *Salmonella typhi*, suspended in storage buffer. Claim 25 is drawn to the size of the said latex particles is 0.88 to 0.90 μm . Claim 26 is drawn the storage buffer is comprised of 50 mM glycine pH 8.5, 1.0% bovine serum albumin, 0.03 % surfactant, 0.1% sodium azide and 0.01% thimerosal. Claim 27 is drawn wherein the antibody is the immunoglobulin fraction, of the hyper immune sera raised in rabbit against the

Art Unit: 1645

recombinant protein expressed by cloning of Flagellin gene sequence specific to *Salmonella typhi* by recombinant DNA technology, suspended in 50 mM phosphate buffer.

Nilsson et al., teach a general method applicable to most proteins that creates a system for highly selective and sensitive protein detection (page 2384, col.1). Nilsson et al., teach antibodies-coated particles used in agglutination assays give more rise to limits of detection in the lower attomole regions of fully optimized systems (page 2384, col.2). Nilsson et al., teach the materials to include: affinity purified antibodies, carboxylated latex particles, 2-(N-Morpholino)ethane-sulfonic acid (MES), ethyl-3(3-dimethylaminopropyl)-carbodiimide (EDC). Bovine serum albumin (BSA), TWEEN 20, a surfactant, Tris, sodium hydroxide, and other reagents (page 2385, col. 1). Nilsson et al., teach covalent coupling of antibodies to latex particles (page 2385, col.1). The carboxylated latex particles (0.9um) were washed in MES buffer, pH 5.5 and resuspended (page 2385, col1). EDC was added to the particles (page 2385. col. 1). Nilsson et al., antibody solution containing BSA was added to the activated particles, coupling the antibodies. Nilsson et al., teach washing with Tris-BSA buffer (page 2385, col. 1-2). Nilsson et al., teach carboxylated latex particles suspended in Tris-BSA buffer (page 2385, col. 2). However Nilsson et al., do not teach using an antibody specific to flagellin gene of *Salmonella typhi* or the preparation of the flagellin gene of *S. typhi* as claimed.

Sukosol et al., teach the monoclonal antibodies specific to the *S. typhi* 52kDa antigen (page 21, col.1). Sukosol et al., using the flagellin antigen to aide in the

Art Unit: 1645

diagnosis of typhoid fever. Sukosol et al., teach specific 52kDa antigen detected by the monoclonal antibodies was *S. typhi* flagellin (page 22, col. 1). The gene was the flagellin gene and the flagellin DNA was amplified using PCR technology (page 22, col.1-3).

Sukosol et al., teach the production of purified protein encoded by a flagellin gene from *Salmonella typhi* (page 21, col. 1). Sukosol et al., teach that the antibodies do not cross react with relation proteins from 11 other bacteria causing enteric fever and enteric fever-like illness (page 21, col.1-2). Sukosol et al., teach the construction and screened for the recombinant clones expressing specific *S. typhi* antigens (page 21, col.3).

Sukosol et al., refer to the teaching of Ekpo et al., (J. Clin. Microbiol. 1990. Vol. 28:1818-1821) entitled *Monoclonal Antibodies to 52kDa Protein of S. typhi* as disclosing monoclonal antibodies from hybrid clones specific for *Salmonella typhi* antigen produced by immunizing mice with affinity-purified *S. typhi* protein.

Salzman et al., teach the production of antibodies with immunization in a host animal, wherein one or more injections of the flagellin protein are administered to produce hyper immune sera (page 12, para. 3). Salzman et al., teach an antibody that binds specifically to flagellin wherein the antibody can be either polyclonal or monoclonal (page, 2, lines 6-8). Salzman et al., teach antibodies to flagellin sequences, polyclonal, monoclonal, humanized, human, fragments and single chain, bispecific, and heteroconjugate antibodies (pages 10-21). Salzman et al., teach the antibodies of the hyper immune sera were isolated by well known techniques (page 13, para. 1). Salzman et al, also teach antibody purification by conventional immunoglobulin purification procedures (page 14, para. 4).

Art Unit: 1645

Fruitstone et al., (US Patent 4,379,847 published April 12, 1983) teach suspending medium for immunologic reactions which includes a salt solution, a buffer, an organic solute and albumin (abstract). Fruitstone et al., teach agglutination reactions have conventionally been in media comprised of saline or albumin solutions where antibodies are washed in suspended in saline solutions but there are disadvantages making evaluation difficult (col. 2, lines 15-30). The suspending medium preferably has azide salts such as the preferred sodium, where sodium azide serves the dual role of affecting ionic strength and acting as a preservative against microbial contamination (col. 2, lines 30-36). Fruitstone et al., teach the preservative function of sodium azide can be particularly beneficial when used with mercury-containing preservatives such as thimerosal (col. 2, lines 36-39). Fruitstone et al., teach the solution includes preservatives, bacteriostats or antibiotics in preserving amounts of thimerosal, sodium azide or combinations thereof (col. 4, lines 22-24). Fruitstone et al., teach bovine serum albumin is preferable because of its availability and cost (col. 3, lines 31-34). The albumin is substantially salt-free or low in salt so as not to contribute appreciably to the ionic strength of the final solution (col. 3, lines 35-37). Fruitstone et al., teach the suspending medium having bovine serum albumin (claim 4); the salt as sodium azide (claims 5-6 and 13-15); the organic solute as glycine claim (9); the pH controlling buffer as phosphate buffer (claims 16-19); the bacteriostat as thimerosal (claim 21); or the suspending medium comprising a preserving amount of thimerosal (claims 23-24). Fruitstone et al., teach in Example IV solutions containing phosphate buffered saline and a preservative, along with the phosphate buffer and albumin (col. 7, lines 12-16).

Art Unit: 1645

Fruitstone et al., teach the solutions can be used with latex particle agglutination test (col. 4, line31-34).

Therefore it would have been prima facie obvious at the time of applicants' invention to apply the antibody specific to the flagellin gene of *Salmonella typhi* as taught by Sukosol et al., the preparation of the of the purified protein as taught by Salzman et al., and the storage buffers as taught by Fruitstone et al., to the method for the preparation of agglutination reagents as taught by Nilsson et al., in order to provide advantageously achieve for agglutination reagent used for diagnosis which overcomes disadvantages associated with agglutination test while providing highly selective and sensitive typhoid detection. One of ordinary skill in the art would have a reasonable expectation of success by incorporating and coating an antibody specific for the flagellin gene of *S. typhi* onto latex particles in order to provide specific binding within a well known and general method applicable to most antibodies to create a system for highly selective and sensitive detection.

Furthermore, no more than routine skill would have been required to incorporate raising hyperimmune sera against the flagellin protein using the flagellin protein of Sukosol et al., when purified the protein that encodes flagellin is already known in the art and Salzman et al., teach antibodies raised against a flagellin polypeptides. Additionally, it would have been prima facie obvious to combine the prior art teachings including Fruitstone et al., to advantageously achieve a suspending medium for latex particle agglutination storage medium that includes sodium azide which has the dual role of affecting ionic strength and acting as a preservative against microbial

Art Unit: 1645

contamination, is known to work beneficially with thimerosal, a preservative or bacteriostat, wherein the solution is also known in the prior art to also contain glycine, bovine serum albumin and surfactants which will overcome the known disadvantages of other suspending mediums. Finally, all the claimed elements, such as an antibody specific to the flagellin gene of *S. typhi*, preparation of the gene, and storage buffer were all known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Response to Arguments

10. Applicant's arguments with respect to claims 23-27 have been considered but are moot in view of the new grounds of rejection. However because several of the same references have been used, the office action will address some of the pertinent arguments.

I) Applicants assert that there is no reason to eliminate Nilsson's second antibody. First, the Nilsson et al., reference clearly teach one type of antibody on each latex particle (see the description of Figure 1). Therefore the general scheme taught by Nilsson et al., meets the limitation of the claim where there is one type of antibody bound to the particle. Furthermore, claims 23 and 24 recite "comprising." The transitional term "comprising" is inclusive or open-ended and does not exclude

Art Unit: 1645

additional, unrecited elements or method steps. See, e.g., *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) (“Comprising” is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) (“comprising” leaves “the claim open for the inclusion of unspecified ingredients even in major amounts”). Therefore applicants’ argument that Nilsson et al., is not obvious because it discloses a process and agglutination reagent with a second antibody is not persuasive since Nilsson et al., teach the same process and reagents; the art may teach unrecited or additional elements not recited by the claims and the claims do not exclude the teachings of Nilsson et al; thus the Nilsson et al., reference is retained.

II) Applicants recite that there is no reason to use a polyclonal antibody instead of a monoclonal one. It is noted that none of the claims recite the use of either a polyclonal or monoclonal antibody. The claims require an antibody specific to the *S. typhi* flagellin gene, Sukosol et al., teach the antibodies specific to the *S. typhi* 52kDa flagellin gene. Applicants’ argument is not found persuasive and the Sukosol et al., reference is retained.

III) Applicants urge that claim 23 recites that recited invention teaches that the washing step is performed with 20 mM MES buffer of pH 5.5 and that the coating is stopped with 1M glycine (pH 11.0) and that the Office Action does not explain why one

Art Unit: 1645

of ordinary skill in the art would use MES buffer and 1M glycine instead of Tris-BSA and Tris-HCL, therefore a *prima facie* case of obviousness has not been established.

However it is noted that Nilsson et al., teach using affinity purified antibodies, carboxylated latex particles, 2-(N-Morpholino)ethane sulfonic acid (MES), ethyl-3(3-dimethylaminopropyl)-carbodiimide (EDC), Bovine serum albumin (BSA), TWEEN 20, Tris, sodium hydroxide, and other reagents. Nilsson et al., teach the carboxylated latex particles were washed in MES buffer, pH 5.5 and resuspended, EDC was added to the particles. Nilsson et al., antibody solution containing BSA was added to the activated particles and stopping the reaction. Therefore the references teach using the same instantly disclosed reagents.

Additionally, it is the position of the Office that differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be *prima facie* obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382 (“The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a

Art Unit: 1645

disclosed set of percentage ranges is the optimum combination of percentages.”); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed.Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). Therefore applicants’ argument is not persuasive.

IV) Applicants argue that there is no teaching of storage buffer. it is noted that only claim 26 recites the ingredients of the storage buffer, while claim 24 is silent as to the components of the storage buffer. Nilsson et al., teach antibody coated carboxylated latex particles suspended in Tris-BSA buffer. Fruitstone et al., teach suspending medium comprising includes a glycine, bovine serum albumin, sodium azide and thimerosal. Therefore applicants’ assertion is not found persuasive.

V) Applicants assert that the prior art was not capable of detecting typhoid at the onset of infection. However Applicant has pointed to the Widal test, culture test, ELISA based test and radioimmunoassay which are all capable of detecting typhoid. Therefore applicants assertion detection was not capable is not found persuasive.

Conclusion

11. No claims allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Robert Mondesi, can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/JaNa Hines/

Examiner, Art Unit 1645

/Mark Navarro/

Primary Examiner, Art Unit 1645